

THE AMENDMENTS

- 1) (Withdrawn) An apparatus for the delivery of an agent into an orifice of an individual and the subsequent removal of the orifice contents from the orifice of said individual, comprising:
- a. an agent delivery assembly, including:
 - i. a means for generating a positive pressure for delivering said agent to a device tip assembly;
 - ii. a means for delivering said agent to the device tip assembly;
 - iii. a means for sealably connecting said agent delivery assembly with said device tip assembly;
 - b. an aspirating assembly, including:
 - i. a means for generating a negative pressure for aspirating said agent and orifice contents from the orifice through the device tip assembly to a storage means;
 - ii. a means for applying said negative pressure to the orifice through the device tip assembly;
 - iii. a means for sealably connecting said aspirating assembly to said device tip assembly; and
 - a. a device tip assembly, including:
 - i. a nozzle means for dispensing said agent received from said agent delivery assembly and aspirating the orifice contents from the orifice to a storage means;
 - ii. a means for sealably connecting said device tip assembly to said agent delivery assembly and said aspirating assembly.
- 2) (Withdrawn) The apparatus of Claim 1, wherein said agent is included in the orifice contents.
- 3) (Withdrawn) The apparatus of Claim 1, further comprising a means for delivering a metered amount of said agent to the orifice.

- A
- 4) (Withdrawn) The apparatus of Claim 3, wherein the means for delivering a metered amount of said agent is a space that is reducible in volume, whereby the reduction of said space is capable of adjusting the amount of said agent drawn into the agent delivery system.
 - 5) (Withdrawn) The apparatus of Claim 1, further comprising a means for delaying the time between delivery of the agent to the orifice and aspirating the agent from the orifice.
 - 6) (Withdrawn) The apparatus of Claim 5, wherein said means for delaying is user-dependent.
 - 7) (Withdrawn) The apparatus of Claim 5, wherein said means for delaying is a mechanical means.
 - 8) (Withdrawn) The apparatus of Claim 1, wherein the agent is a solution.
 - 9) (Withdrawn) The apparatus of Claim 1, wherein the agent is chosen from the group consisting of a powder, a gel, a bead, a liposome, a microemulsion and a micelle.
 - 10) (Withdrawn) The apparatus of Claim 1, wherein the orifice is a bodily opening.
 - 11) (Withdrawn) The apparatus of Claim 1, wherein the orifice is a nose.
 - 12) (Withdrawn) The apparatus of Claim 1, wherein the orifice is chosen from the group consisting of an opening in the cutaneous layer, a portal device, a catheter and an access device.
 - 13) (Withdrawn) The apparatus of Claim 1, wherein said agent is stored in a first reservoir sealably connected to said agent delivery assembly.

- 14) (Withdrawn) The apparatus of Claim 13, wherein said first reservoir is removable.
- 15) (Withdrawn) The apparatus of Claim 1, further comprising storing said agent and orifice contents aspirated from the orifice in a second reservoir.
- 16) (Withdrawn) The apparatus of Claim 15, wherein said second reservoir is contained within the aspirating assembly.
- 17) (Withdrawn) The apparatus of Claim 15, wherein said second reservoir is contained within the device tip assembly.
- 18) (Withdrawn) The apparatus of Claim 1, further comprising a reservoir capable of storing said agent prior to delivery of the agent to the orifice and storing said agent aspirated from the orifice.
- 19) (Withdrawn) The apparatus of Claim 1, wherein the means for generating a positive pressure is mechanical or electrical.
- 20) (Withdrawn) The apparatus of Claim 1, wherein the means for generating a positive pressure is a compressed air cartridge.
- 21) (Withdrawn) The apparatus of Claim 8, wherein said solution is atomized prior to delivery to the orifice.
- 22) (Withdrawn) The apparatus of Claim 1, wherein the means for generating a negative pressure is mechanical or electrical.
- 23) (Withdrawn) The apparatus of Claim 22, wherein the means for generating a negative pressure is a vacuum pump.
- 24) (Withdrawn) The apparatus of Claim 1, further comprising a means for adjusting the

level of negative and positive pressure applied to the orifice.

- 41
- 25) (Withdrawn) The apparatus of Claim 24, wherein the means for adjusting the level of negative and positive pressure applied to the orifice comprises at least one adjustable vent contained within the device tip assembly, said adjustable vent is capable of venting the internal pressure of the apparatus to the external environment.
- 26) (Withdrawn) The apparatus of Claim 24, wherein the means for adjusting the level of negative and positive pressure comprises a means for controlling the level of negative and positive pressure generated.
- 27) (Withdrawn) The apparatus of Claim 24, wherein the means for adjusting the level of negative and positive pressure applied to the orifice comprises at least one adjustable vent contained within the device tip assembly and a means for controlling the level of negative and positive pressure generated.
- 28-37) (Cancelled)
- 38) (Withdrawn) An apparatus for the delivery of an agent into an orifice of an individual and the subsequent aspiration of the orifice contents from the orifice of said individual, wherein said orifice contents removed from said individual are analyzed for the presence of a target, comprising:
- a. an agent delivery assembly, including:
 - i. a means for generating a positive pressure for delivering said agent;
 - ii. a means for delivering said agent to a device tip assembly;
 - ii. a means for sealably connecting said agent delivery assembly to said device tip assembly;
 - b. an aspirating assembly, including:
 - i. a means for generating a negative pressure for aspirating the orifice contents from the orifice through the device tip assembly;
 - ii. a storage means for the aspirated orifice contents, whereby said storage

- means is sealably connected and removable from said apparatus;
 - iv. a means for sealably connecting said aspirating assembly to said device tip assembly;
 - c. a device tip assembly, including:
 - i. a nozzle means for dispensing said agent received from said delivery assembly and aspirating the orifice contents from the orifice;
 - ii. a means for sealably connecting said device tip assembly to said agent delivery assembly and said aspirating assembly.
- 39) (Withdrawn) The apparatus of Claim 38, wherein said agent is included in the orifice contents.
- 40) (Withdrawn) The apparatus of Claim 38, further comprising a means for delivering a metered amount of said agent to the orifice.
- 41) (Withdrawn) The apparatus of Claim 38, further comprising a means for delaying the time of delivery of the agent to the orifice and aspirating the agent from the orifice.
- 42) (Withdrawn) The apparatus of Claim 38, wherein the agent is a solution.
- 43) (Withdrawn) The apparatus of Claim 38, wherein the orifice is a nose.
- 44) (Withdrawn) The apparatus of Claim 38, wherein said storage means for storing the orifice contents aspirated from the orifice is contained within the device tip assembly.
- 45) (Withdrawn) The apparatus of Claim 42, wherein said solution is atomized prior to delivery to the orifice.
- 46) (Withdrawn) The apparatus of Claim 38, further comprising a means for adjusting the level of negative and positive pressure applied to the orifice.

- 47) (Withdrawn) The apparatus of Claim 38, wherein said target is chosen from the group consisting of metabolites, chemicals, organic compounds, inorganic compounds, organic elements, inorganic elements, foreign particulate matter, pathogens and organisms.
- 48) (Withdrawn) The apparatus of Claim 38, further comprising the assaying of microbiological, biochemical, metabolites, chemical or foreign particulates after removal of said storage means from the apparatus.
- 49) (Withdrawn) The apparatus of Claim 38, further comprising an assay means contained within the apparatus chosen from the group consisting of microbiological organisms, pathological organisms, metabolites, biochemical agents, chemical agents and foreign particulate matter.
- 50) (Withdrawn) The apparatus of Claim 38, wherein said assay means is chosen from the group consisting of immunochemical assays, biochemical assays and chemical assays.
- 51) (Withdrawn) A method for the delivery of at least one agent into an orifice and the subsequent removal of the orifice contents, comprising:
 - a. providing a positive pressure means for delivery of said agent to the orifice;
 - b. delivering said agent to the orifice; and
 - c. providing a negative pressure means for aspiration of the orifice contents to a storage means contained within the apparatus.
- 52) (Withdrawn) The method of Claim 51, wherein said agent is included in the orifice contents.
- 53) (Withdrawn) The method of Claim 51, wherein said positive pressure means and said negative pressure means is electrical or mechanical.
- 54) (Withdrawn) The method of Claim 51, wherein said mechanical means is a pump.

- 55) (Withdrawn) The method of Claim 51, wherein said agent is a solution.
- 56) (Withdrawn) The method of Claim 51, wherein said agent is chosen from the group consisting of a powder, a gel, a bead, a liposome, a microemulsion and a micelle.
- 57) (Withdrawn) The method of Claim 51, wherein the orifice is a nose.
- 58) (Withdrawn) The method of Claim 51, wherein the orifice is a bodily opening.
- 59) (Withdrawn) The method of Claim 51, wherein the orifice is chosen from the group consisting of an opening in the cutaneous layer and a portal or access device into the cutaneous layer of said individual.
- 60) (Withdrawn) The method of Claim 51, wherein said storage means is contained within said apparatus.
- 61) (Withdrawn) The method of Claim 51, wherein said storage means is sealably connected and removable from said apparatus.
- 62) (Withdrawn) A method for the detection of a target present within an orifice, whereby an agent is delivered into the orifice and the orifice contents are subsequently aspirated from the orifice, comprising:
- a. providing a positive pressure means for delivery of said agent to the orifice;
 - b. delivering said agent to the orifice;
 - c. providing a negative pressure means for aspiration of the orifice contents to a storage means; and
 - d. assaying of the orifice contents contained within said storage means;
- whereby said orifice contents are assayed for the presence of a target.
- 63) (Withdrawn) The method of Claim 62, wherein said agent is included in the orifice contents.

- 64) (Withdrawn) The method of Claim 62, wherein said target is chosen from the group consisting of metabolites, chemicals, organic compounds, inorganic compounds, organic elements, inorganic elements, foreign particulate matter, pathogens and organisms.
- 65) (Withdrawn) The method of Claim 62, wherein said positive pressure means and said negative pressure means is electrical or mechanical.
- 66) (Withdrawn) The method of Claim 62, wherein said agent is a solution.
- 67) (Withdrawn) The method of Claim 62, wherein the orifice is a nose.
- 68) (Withdrawn) The method of Claim 62, wherein said storage means is sealably connected and removable from said apparatus.
- 69) (Withdrawn) The method of Claim 62, further comprising the assaying for biological or chemical substance or organism present within the orifice after removal of said storage means from the apparatus.
- 70) (Withdrawn) The method of Claim 62, further comprising an assay means contained within the apparatus for the detection of a biological or chemical substance or organism present within the orifice.
- 71) (Withdrawn) The method of Claim 62, wherein said assay means is chosen from the group consisting of immunochemical assays, biochemical assays or chemical assays.
- 72) (New) An apparatus for the delivery of an agent into an orifice and the subsequent aspiration of contents from the orifice, comprising:
- a. a bulb to hold said agent in a first internal chamber, said bulb capable of generating positive pressure when in a compressed state, and negative pressure when released from said compressed state;

- b. a first tube positioned internally within said bulb, said first tube extending into the internal chamber of the bulb at a first end; and
- c. a device tip operatively connected at a first end to the bulb and to the first tube at a second end of said first tube, said device tip having a second end contacting said orifice;
- d. a first valve and bypass port means, wherein said valve and bypass means acts to regulate flows through said tube and regulates flows and pressures from the compression and release of said bulb; and
- e. a second internal chamber within said device tip, the second internal chamber operatively connected to the second end of the device tip through a first pathway, the first pathway connected to the first internal chamber of the bulb through a gas separating means and a second valve means;

wherein said second valve means is capable of regulating pressures and flows from the compression and release of said bulb, said gas separating means is capable of limiting passage of aspirated contents into the first internal chamber and said device tip is capable of being removed from said bulb.

73. (New) The apparatus of Claim 72, wherein the first pathway is a second tube operatively connected to the second end and second internal chamber of the device tip.
- 74) (New) The apparatus of Claim 72, further comprising a filter on the second valve means.
- 75) (New) The apparatus of Claim 72, further comprising a means for delivering a metered amount of said agent to the orifice.
- 76) (New) The apparatus of Claim 72, further comprising a means for delaying the time between the compression and release of said bulb.
- 77) (New) The apparatus of Claim 72, wherein the agent is a solution.
- 78) (New) The apparatus of Claim 72, wherein the orifice is a nose.